



UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

YL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

08/896,821 07/18/97 QUAY

S SNUS125

HM12/0721

EXAMINER

W. PATRICK BENGTSSON  
LIMBACH AND LIMBACH  
2001 FERRY BUILDING  
SAN FRANCISCO CA 94111

HOLLINDEN, G

ART UNIT

PAPER NUMBER

1616

18

DATE MAILED:

07/21/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**SUPPLEMENTAL  
Office Action Summary**

Application No. <b>08/896,821</b>	Applicant(s) <b>Quay</b>
Examiner <b>Gary E. Hollinden</b>	Group Art Unit <b>1616</b>

- Responsive to communication(s) filed on May 24, 1999
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

- Claim(s) 15-35 is/are pending in the application.
- Of the above, claim(s) 15-29 and 32-35 is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 30 and 31 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claims \_\_\_\_\_ are subject to restriction or election requirement.

**Application Papers**

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been
- received.
  - received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit 1616

This Office Action is a response to the supplemental amendment filed on May 24, 1999. Since the supplemental declaration was filed before the final rejection was mailed but was not considered, this supplemental Office Action is being sent and the period for response will be restarted to the date of this action. Currently, Claims 15-35 are pending in this application and claims 31 and 32 will be examined on their merits.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 30<sup>1</sup> and 31 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time that application was filed, had possession of the claimed invention for reasons of record stated in the Office Action dated September 22, 1998.

Applicant's arguments filed on May 24, 1999 have been fully considered but they are not deemed to be persuasive. In particular, Applicant has provided another declaration by Dr. Hilpert wherein she essentially states that it is her opinion that one of ordinary skill would have understood that the original specification would have conveyed the instant claimed species of perfluoropropane microbubbles combined with human protein. Examiner provided reasons why such a line of argument was unpersuasive in the Office Action mailed on June 21, 1999. The instant declaration provides little further weight since it merely represents the opinion of Dr. Hilpert and does not provide any factual evidence. As stated in *In re Payne*:<sup>2</sup>

---

<sup>1</sup>Applicant correctly notes that claim 30 is not limited to human protein as the shell material. However, claim 30 is currently only being examined to the extent that it reads upon the elected species (¶ 2 of the Office Action dated September 22, 1998) and as such, is limited to human protein for purposes of examination. As noted above, when the instant species becomes allowable, it will be fully examined.

<sup>2</sup>203 USPQ 245, CCPA 1979

Art Unit 1616

"Arguments of counsel unsupported by competent factual evidence of record are entitled to little weight; it is incumbent upon applicant to introduce affidavits or other factual evidence in support of his position, to successfully rebut examiner's prima facie case of enablement; facts, such as test data demonstrating inoperativeness of prior art analogy, or facts set forth in Patent Rule § 132 affidavit of expert in field suggesting inoperativeness are highly probative, examiner's prima facie case of enablement must stand, where applicant has submitted no such evidence."

As stated in the previous Office Action, the factual record in the instant case simply does not support the proposition that Applicant possessed claim designated species at the time of the original invention

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 30 and 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. patent nos. 5,409,688, 5,393,524, 5,573,751, 5,558,854, 5,558,094, 5,558,855, and 5,558,853 because the instant elected composition is drawn to a specific sub-genus which would be encompassed within the broader claims of the cited patents for reasons of record stated in the Office Action dated September 22, 1998.

Applicant's agreement to file an appropriate terminal disclaimer filed on March 25, 1999 is acknowledged.

Claims 30-and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending application serial no. 08/466,104, 08/646,910, 08/710,849, 08/770,522, 08/745,256, and 08/900,986. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant elected composition is drawn to a specific sub-genus which would be encompassed

Art Unit 1616

within the broader claims of the cited applications for reasons of record stated in the Office Action dated September 22, 1998.

Applicant's agreement to file an appropriate terminal disclaimer filed on March 25, 1999 is acknowledged.

The obviousness-type double patenting rejection, whether of the obviousness type or non-obviousness type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent<sup>3</sup>.

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 30 and 31 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of the claims of copending application Serial No. 08/710,849. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented for reasons of record stated in the Office Action dated September 22, 1998.

Applicant's arguments filed on March 25, 1999 have been fully considered. Applicant is apparently making reference to the fact that if 08/710,849 is still pending when the instant claims become allowable, then this rejection should be withdrawn in this case and maintained in '849.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. § 101 which states that "whoever invents or discovers any new

---

<sup>3</sup>*In re Thorington*, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 214 USPQ 761 (CCPA 1982); *In re Longi*, 225 USPQ 645 (CA FC 1985); and *In re Goodman*, 29 USPQ 2010 (CA FC 1993).

and useful process ... may obtain a patent therefor ...". Thus, the term "same invention," in this context means an invention drawn to identical subject matter<sup>4</sup>.

A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are not longer coextensive in scope. The filing of terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. § 101.

In view of the objections /rejections to the pending claims set forth above, no claims may be allowed at this time.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to the Group 1600 fax machine at 703/308-4556. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30; November 15 1989.

Any inquiry concerning this Office Action or any earlier Office Actions in this application should be directed to Dr. Gary E. Hollinden whose telephone number is 703/308-4521. Dr. Hollinden's office hours are from 6:30 am to 3:00 pm on Monday through Friday.

---

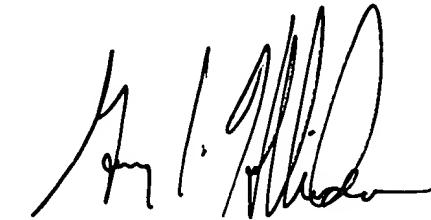
<sup>4</sup>*Miller v. Eagle Mfg.* 151 U.S. 186 (1894); *In re Ockert*, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 164 USPQ 619 (CCPA 1970).

08/896,821

-6-

Art Unit 1616

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 703/308-1235.



**Gary E. Hollinden, Ph.D.  
Primary Examiner  
Group 1600**